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Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane Room 1061 Rockville, MD 20852

Re:

Docket No. 97N-484S: Suitability Determination for Donors of Human Cellular

and Tissue-Based Products

To whom it may concern:

I write to submit comments on behalf of Lambda Legal Defense and Education Fund, the American Civil Liberties Union, the Gay and Lesbian Medical Association, the Human Rights Campaign, the National Center for Lesbian Rights, the National Gay and Lesbian Task Force, Parents and Friends of Lesbians and Gays, Rainbow Flag Health Services, and the Sperm Bank of California regarding the Food and Drug Administration's proposed rules on "Suitability Determination for Donors of Human Cellular and Tissue-Based Products." We urge the Food and Drug Administration to amend the proposed regulations to (1) allow all recipients of directed donations to use fresh sperm by signing a written waiver exempting themselves from the sixmonth quarantine period regardless of whether the recipient has been sexually intimate with the donor, and (2) eliminate the physician consent requirement for directed donations from "unsuitable" donors. We also (3) commend the FDA for permitting directed donations from "unsuitable" donors, and (4) ask the FDA to adopt a less value-laden term to describe reproductive tissue donors whose behavioral or medical histories raise particular concerns.

The final regulations should adhere to two central principles. First, the regulations should prioritize patient autonomy when making choices about reproduction and reproductive health. Autonomous decision-making is a prerequisite for the meaningful exercise of informed consent, and should guide the FDA as it moves into this emerging area. Second, the regulations should ensure a health care environment that allows wide access – based on sound medical judgments – to the full potential of available reproductive technologies. Donor insemination regulations should recognize the diversity of the population seeking care, and allow women maximum flexibility in choosing the biological father of their child.

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¹ <u>See</u> 64 Fed. Regis. 52696 (September 30, 1999).

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I. The Regulations Should Allow Any Informed Recipient Who Has Waived the Quarantine Period Access to Fresh Sperm from Directed Donors Regardless of the Relationship Between the Donor and the Recipient

A. Current Proposal

Under proposed 21 CFR 1271.85(d), all reproductive tissue donations from directed donors, both "suitable" and "unsuitable," are subject to a six-month quarantine and retest procedure, except for directed donation by a "sexually intimate partner of the recipient for reproductive use" as defined in proposed 21 CFR § 1271.90(a)(2). As a result, only recipients of directed donations from donors who are sexually intimate with the recipient are able to use fresh sperm. All other recipients are forced to use cryopreserved tissue.

B. Suggested Change

Proposed 21 CFR §1271.85(d) should be revised to allow all recipients of directed donations to use fresh sperm, regardless of whether they have been sexually intimate with the directed donor, by permitting recipients of directed donations to sign a written waiver exempting themselves from the six-month quarantine period. All directed donation recipients should be fully informed of the risks associated with fresh sperm.

Our suggested approach is not new. The California Health and Safety Code already applies similar provisions to sperm banks in California, allowing for a waiver of the quarantine period for directed donations of reproductive tissue "if the recipient is informed of the requirements for testing donors under this section and signs a written waiver." The policy provides Californians with meaningful reproductive choice without sacrificing the safety of recipients.³

² Cal. Health & Safety Code § 1644.5(c)(1).

³ There are only twelve known cases of HIV transmission from inseminated donor semen. Of these cases, six are from the United States, four in Australia, and two in Canada. Mary E. Guinan. Artificial Insemination by Donor: Safety and Secrecy. Journal of the American Medical Association 1995;273: 890. Among the six American cases, five of the six inseminations were initiated prior to the institution of widespread HIV testing in July 1985, while the sixth involved a woman who was inseminated with processed sperm from her husband, who was known to be HIV positive at the time of insemination. See PM Wortley et al. Donor Insemination and Human Immunodeficiency Virus Transmission. Obstet Gyencol 1998;91: 515-18; CDC. HIV-1 Infection and Artificial Insemination with Processed Semen. MMWR 1990;39:249, 255-56. There are two other possible American cases, one of which involved

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C. Rationale

By allowing only "sexually intimate couples" to waive the quarantine period for directed donations, the proposed regulations deprive many directed donation recipients who wish to use medical facilities of the benefits associated with fresh sperm without a sound scientific basis for that exclusion. The assumption that sexually intimate couples have already exposed themselves to risk for HIV⁴ – and therefore that the use of fresh sperm during insemination does not carry with it any additional health risks – is inherently flawed. Moreover, given the greater likelihood of conception with fresh rather than frozen sperm and the minimal risk of HIV transmission, all recipients should be given the opportunity to assert their autonomy and exercise their informed consent by assessing the comparative risks and benefits of fresh sperm.

Sexual intimacy, in and of itself, does not mean that a directed donation recipient has already exposed herself to any risk for HIV and other blood-borne pathogens from her partner. The use of condoms and other safe sex practices can lower or eliminate the risk of HIV transmission. Likewise, high risk behaviors can increase risk. Depending upon the behavioral histories of the parties involved, a directed donor with a history of MSM conduct who has not been sexually intimate with the recipient could well present a far smaller risk for HIV transmission through fresh sperm than a directed donor who has been sexually intimate with the recipient.

Rather than facing limitations based solely upon broad and scientifically inaccurate assumptions about behavior and HIV risk, a recipient – after being presented with an honest medical appraisal of the risks associated with the use of fresh sperm – should be able to make her own decision about whether the risks of waiving the quarantine period outweigh the benefits, regardless of her relationship to the directed donor. Recipients are the ones best situated to evaluate their individual considerations, and their degree of comfort with different levels of risk. So long as the recipient is aware of any risks associated with the use of fresh sperm and of the HIV test results of the directed donor at the time of donation, the recipient should maintain the ability to assert her autonomy and use fresh sperm by signing a written waiver.

inseminations from May 1978-February 1986; the time frame of the other is unknown, but the date of AIDS diagnosis was December 1988. <u>Sec</u> Wortley, <u>supra</u>.

⁴ See 64 Fed. Regis. 52707 ("[i]n this case, the recipient will likely have been routinely exposed to the donor's semen or other body fluids").

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Moreover, the benefits associated with the use of fresh sperm are abundantly clear from the medical literature,⁵ and should be available to all recipients of directed donors who choose to waive the quarantine period. Furthermore, the six-month quarantine could have a serious effect

⁵ See RS Sidhu et al. Effects of Cryopreserved Semen Quality and Timed Intrauterine Insemination on Pregnancy Rate and Gender of Offspring in a Donor Insemination Program. Journal of Assisted Reproduction and Genetics 1997; 14: 531 at 534 ("[c]ompared to fresh semen, frozen-thawed semen has a diminished capacity to achieve pregnancy after donor insemination"); BM Kang & TJ Wu, Effect of Age on Intrauterine Insemination with Frozen Donor Sperm, Obstet Gynecol 1996;88:93-8 at 93 ("quarantined, cryopreserved sperm results in a decreased cycle fecundity compared with fresh semen"); W Byrd et al, Intrauterine Insemination With Frozen Donor Sperm: A Prospective Randomized Trial Comparing Three Different Sperm Preparation Techniques, Fertility & Sterility 1994;62:850-56 at 851 ("[c]ryopreservation of sperm results in cryodamage to the spermatozoa and decreased fecundity of the spermatozoa"); WW Hurd et al. Comparison of Intracervical, Intrauterine, and Intratubal Techniques for Donor Insemination, Fertility & Sterility 1993;59:339-42 at 339 ("[u]nfortunately, the cycle fecundity rates after intracervical insemination (ICI) with cryopreserved sperm is less than half that found after insemination with fresh semen"); PB Marshburn et al. Spermatozoal Characteristics From Fresh and Frozen Donor Semen and Their Correlation With Fertility Outcome After Intrauterine Insemination. Fertility & Sterility 1992;58:179-86 at 185 ("[t]he frozen-thawed semen compared with fresh semen has a diminished capacity to achieve pregnancy after donor insemination"); W Byrd et al. A Prospective Randomized Study of Pregnancy Rates Following Intrauterine and Intracervical Insemination Using Frozen Donor Sperm. Fertility & Sterility 1990;53:521 at 525 ("cryopreserved sperm have a lowered fecundity rate when contrasted to fresh sperm. It is assumed that this decrease is primarily because of damage to the sperm during processing and freezing"); CA Brown et al. Improved Cryopreserved Semen Fecundability in an Alternating Fresh-Frozen Artificial Insemination Program. Fertility & Sterility 1988; 50:825-27 (finding that fresh semen had a superior fecundability rate to frozen semen). MA Richter, Artificial Donor Insemination: Fresh Versus Frozen Semen; The Patient As Her Own Control, Fertility & Sterility 1984;41:277 at 279 (confirming "the general belief that fresh semen is more effective than cryopreserved semen in producing pregnancies").

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on pregnancy rates for older recipients⁶ and on directed donors who have a low number of post-freeze motile sperm.⁷

The proposed regulations would also have a disparate, negative impact on lesbian recipients, the overwhelming majority of whom are not sexually intimate with their donors. As more lesbians and gay men make the decision to become parents – and rely upon donor insemination to structure their families – the availability of accessible and effective reproductive options becomes even more vital for our community. Permitting all recipients of directed sperm donations an informed waiver of the quarantine period would ensure that all recipients have access to quality health care that meets their needs.

II. Doctor Consent to Waiver of Quarantine Period for Directed Donations

A. Current Proposal

Under proposed 21 CFR §1271.65(b)(3)(iii), a physician's consent is required before a recipient can receive a directed donation from an "unsuitable" donor.

B. Suggested Change

Proposed 21 CFR §1271.65(b)(3)(ii) should be deleted. In order for a recipient to receive a donation from a directed donor, the FDA should not require the consent of the physician provided that the other requirements of proposed §1271.65(b)(3) are satisfied. We do, however, support proposed 21 CFR §1271.65(b)(3)(i)'s requirement that the physician be notified of the testing and screening results, and the procedure in proposed 21 CFR §1271.65(b)(3)(iii-iv) mandating that a recipient provide informed consent before proceeding with a directed donation from an "unsuitable" donor.

⁶ See, e.g. BM Kang & TJ Wu, Effect of Age on Intrauterine Insemination with Frozen Donor Sperm, Obstet Gynecol 1996;88:93-8 (finding that the age of a recipient is a significant predictor of fertility outcome for intrauterine insemination of frozen donor sperm).

⁷ See, e.g., BA Keel et al. Effects of Cryopreservation on the Motility Characteristics of Human Spermatozoa. Journal of Reproduction & Fertility 1987;81:213-220 at 215 ("[c]ryopreservation resulted in significant . . . reductions in [sperm] velocity, motility index and motile density").

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C. Rationale

As currently drafted, proposed 21 CFR §1271.65(b)(3)(ii) allows a physician to withhold his or her consent to a directed donation from an "unsuitable" donor without any restrictions on the exercise of that consent, and regardless of whether the recipient has already given her informed consent to proceed with the insemination. This provision is problematic for three reasons.

First, by allowing physicians to withhold their consent to directed donations from "unsuitable" donors without any restrictions on the exercise of that consent, the proposed regulations contradict a fundamental tenet of medical ethics: the patient's right to make his or her own decisions about medical treatment. The American Medical Association's ethics opinion on informed consent makes this abundantly clear: "[t]he patient should make his or her own determination on treatment." A process that affirms the recipient's control over medical decisions is particularly important when the decision involves something as personal as the choice of a child's biological father. Granting a physician unfettered discretion over such an important choice undermines the value of informed consent and threatens patient autonomy.

A separate physician consent provision is also unnecessary. The conduct of physicians is guided by generally applicable ethical standards and by federal and state law. These standards would continue to apply regardless of whether an explicit physician consent provision is included within the regulations. A separate provision suggests that a physician's ability to withhold consent is somehow broader in a donor insemination context. But since donor insemination is subject to the same guidelines and regulations that govern other medical procedures, there is no need to create any unnecessary confusion among patients and doctors about the scope of physician consent with regard to this procedure.

Furthermore, the physician consent requirement – without any limitations – creates the danger that some recipients will be wrongfully denied their ability to exercise informed consent because the physician withholds consent for invalid reasons, such as the donor's or recipient's sexual orientation, marital status, or HIV status. The existence of sexual orientation discrimination within the medical profession has been well documented, despite widely accepted ethical guidelines that prohibit the denial of care based upon the sexual orientation of a

⁸ AMA Code of Medical Ethics, Current Opinion 8.08 (issued March 1981).

⁹ See, e.g., New York City Department of Health, Report on the Health Status of Gay Men and Lesbians in New York City (June 1999) at 48-57; Schatz, B. & O'Hanlan, K., Anti-Gay Discrimination in Medicine. Gay and Lesbian Medical Association, San Francisco, CA (1994) at 14-18.

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patient.¹⁰ In the context of donor insemination, Lambda and other legal organizations that serve the gay community have heard numerous anecdotes of recipients who were denied insemination services because of their sexual orientation or marital status.

III. The Proposed Regulations Are An Improvement Over Current Standards

We commend the FDA for providing a mechanism that allows recipients of directed donations the freedom to choose the biological father of their children. Specifically, we endorse proposed 21 CFR §1271.65(b)(1)(ii), which provides an exception allowing for directed donations of reproductive tissue by "unsuitable" donors. And, with the notable exception of the doctor consent provision discussed above, we endorse the other components of the procedure developed to allow directed donations by "unsuitable" donors outlined in 21 CFR §1271.65(b)(3)(i),(iii-iv).

Donor insemination currently operates under a loose patchwork of state regulations and industry practices. By creating a uniform regulatory structure for donor insemination, the FDA is adding clarity to a process that has created confusion for doctors and patients alike. Moreover, by respecting the recipient's autonomy and allowing inseminations by a full range of directed donors, both "suitable" and "unsuitable," the FDA has taken an important step in removing one of the major obstacles to the creation of families for lesbians, gay men, and others who might choose donors deemed "unsuitable."

IV. The FDA Should Abandon the Use of the Terms "Suitable" and "Unsuitable" When Discussing Reproductive Tissue Donation

Finally, we urge the FDA to abandon the use of the terms "suitable" and "unsuitable" to describe different types of reproductive tissue donors. Since "unsuitable" donors are allowed to serve as directed donors for reproductive tissue under the proposed regulations, the term "unsuitable" is inaccurate and may cause confusion or prejudice involving recipients, donors, or practitioners. While we recognize the need to distinguish between donors with different medical histories, as well as the need to adopt terms that make sense given the various policies governing other types of tissue donation, the use of less value-laden terms such as "higher risk" – at least in the context of reproductive tissue – would add clarity and reinforce the inclusive nature of the FDA's directed donor policy.

¹⁰ See AMA Code of Medical Ethics, Current Opinion 9.12 (issued July 1986, updated June 1994 and June 1998) ("physicians who offer their services to the public may not decline to accept patients because of . . . sexual orientation").

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Thank you for your time and attention. If you have any questions or need additional information, I can be reached by phone at (212) 809-8585 or by e-mail at dgewirtzman@lambdalegal.org.

Sincerely,

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